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RECOMMENDATIONS FOR THE USE OF PATIENT REPORTED OUTCOMES TO ASSESS TREATMENT EFFICACY IN CLINICAL GUIDANCE DOCUMENTS RELEASED BY THE FDA AND EMEA

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OBJECTIVES: EMEA's reflection paper on health related quality of life (HRQL) and FDA's draft guidance on patient-reported outcomes (PRO) were published in 2006. Both discuss the use of PROs and HRQL, but leave questions about what PRO information regulators value for decision-making. The objective of this study was to use recent clinical guidance documents to understand and compare FDA and EMEA use of PRO endpoints for regulatory decisions. **METHODS:** PRO endpoints mentioned in clinical guidance documents published by the FDA and EMEA from January 2006 through March 2009 were extracted. Analysis compared the number and nature of FDA and EMEA recommendations regarding PRO endpoints. **RESULTS:** PRO were mentioned in 12 FDA and 21 EMEA clinical guidance documents published between January 2006 and March 2009, reflecting 46% and 35% of the clinical guidance documents published by FDA and EMEA, respectively. FDA and EMEA each mentioned PRO symptom measures in nine clinical guidances, but HRQL was mentioned as an appropriate endpoint in only three FDA guidances compared with 16 EMEA guidances. Specific PRO instruments were more often mentioned by name in EMEA guidance documents (11 EMEA vs. 1 FDA), but neither agency mandated a particular measure must be used. For both agencies, the level of detail provided regarding recommendations for implementing PROs varied widely among guidances; typically, EMEA guidance on PRO endpoints was more detailed. Trends noted for indications and therapeutic areas will be presented. **CONCLUSIONS:** Clinical guidance documents demonstrate that regulators value the patient perspective. FDA's focus tends to be on PRO symptom assessment whereas EMEA often refers to HRQL and is more likely to specify instruments for PRO endpoints. These results indicate that FDA and EMEA use PRO-based evidence but the agencies differ in what type of PRO endpoints they encourage for regulatory decision-making.

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ADHERENCE OF PHARMACOECONOMIC STUDIES SUBMITTED FOR THE REIMBURSEMENT AND PRICING SYSTEM IN 2008 TO THE CZECH PHARMACOECONOMIC GUIDELINES

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OBJECTIVES: To assess the quality of the health economic analysis (HEA) submitted for the reimbursement and pricing system in the Czech Republic in 2008. **METHODS:** Assessing quality of health economic guidelines (budget-impact analyses not included) submitted for the new molecules to the State Institute for Drug Control via the online system. The highly innovative **medicines were excluded as for those entities** there are no obligation to submit the HEA. The concordance with check-list of the Czech pharmacoeconomic guidelines (12 aspects of the HEA) was investigated. **RESULTS:** HEAs of 16 New Chemical Entities were investigated. A total of 87.5% of HEAs were submitted from the payer perspective, 18.8% from society perspective. The most common appl**ied time horizon was 0–12 months (47%). Comparator** was appropriately chosen in 81%. Analyses used were Cost-Utility analysis (47.6%), Cost-effectiveness analysis (28.6%) and Cost-Minimalisation analysis (23.8%). Models were used in 56% (including decision-tree, Markov and special models). The utility data were obtained from clinical trials (100%), Summary of Product Characteristic (SPC) (14%) and guidelines (7%). Data for the direct costs were obtained from price list of insurance companies (100%), published data (57%), etc. The most used type of costs were therapy, application, adverse side effects and in- and outpatient days. As an effectiveness measure QALYs were used in 43%, LYGs in 19% and surrogate clinical parameters in 38%). ICER was applied in 75%. Analysis of sensitivity was used only in 62.5%. Discounting of costs and outcomes was used in 56%; 67% of those used 3% discounting of both costs and outcomes. **CONCLUSIONS:** The assessment of the quality of the submitted HEA in the Czech Republic showed relatively short time horizon used, occasional problems with the choice of comparator, use of QALY in more then half HEA and insu**fficient** application of the analysis of sensitivity. The data from real-practice should be used more.

HEALTH CARE USE & POLICY STUDIES – Beyond Drug Intervention

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COST-EFFECTIVENESS OF HEALTH PROMOTING INTERVENTIONS

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OBJECTIVES: Recently, the Flemish government has formulated several health objectives regarding healthy nutrition and physical exercise following recommendations from the WHO and the European Commission. The purpose of this study **was to** evaluate the cost-effectiveness of 16 potential health promoting interventions, related to these objectives. Interventions were aimed at the local community, the child environment, the workplace, health care providers and at information and communication channels. **METHODS:** A literature search was performed to determine the effectiveness of the interventions on short term intermediate outcome parameters and on diabetes and cardiovascular and oncologic events. Afterwards modeling was performed to predi**ct the expected lifetime results in avoided DALY's. The simulation was carried** out on 4 age categories, i.e. 40, 50, 60 and 70-years old, assuming a 10-year implementation of the intervention. For the interventions aimed at children, a projection was made to later adult life, based on literature. In addition, the investments required for implementing the interventions during a 10-year period, and the costs of avoided events were calculated from a societal perspective. This allowed calculating the Return On Investment (ROI) and the full benefit cost ratio, assuming a value of €30,000 for avoiding one DALY. **RESULTS:** For the interventions aimed at the local community, the child environment, the workplace, health care providers and information and communication channels the average ROI equals to 9.59(1.32–22.44); 0.37(0.01–1.68); 1.98(0.56–4.52); 9.25(2.71–**17.20); and 58.02(14.72–125.55) Euro per invested** euro respectively. About half of the interventions have a positive ROI. The average full benefit cost ratio amounted to 36.36(5.89–71.36); 3.08(0.16–10.56); 9.14(3.33–20.04); 37.24(15.97–54.54); and 233.63(86.64–398.17) respectively. Only two interventions (aimed at the child environment) appeared not to be cost-beneficial for any age groups. **CONCLUSIONS:** Implementing interventions to promote a healthy lifestyle could generate a substantial amount of health gain leading to very beneficial benefit/cost ratios for a majority of interventions.

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HOW DOES THE HEALTH IMPROVEMENT NETWORK (THIN) DATA ON PREVALENCE OF CHRONIC DISEASES COMPARE WITH NATIONAL FIGURES?

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OBJECTIVES: Primary care patient databases are increasingly used within many different research areas. These databases reflect everyday care provided to patients in a sample of practices. Thus, when used for research, information on generalisability to the general population is important. This study compared chronic condition prevalences from a UK primary care database, THIN, with national figures. **METHODS:** The study population was selected from THIN Data. The National Health Service (NHS) Quality and Outcomes Framework (QOF, a national standard used for the measurement of primary care outcomes for payment) disease/drug codelists and rules were used to derive crude prevalence of chronic diseases. Prevalence and 95% confidence intervals (CIs) were derived as of February 14, 2007, March 14, 2007, and April 1, 2007 from practices in Scotland/Northern Ireland, England, and Wales, respectively, to match QOF methodology. National QOF 2006/2007 prevalence data were used for comparison. **RESULTS:** THIN population included 2,783,593 people. The atrial fibrillation crude prevalence was in THIN 1.42%(±0.01%) versus 1.31% nationally. For asthma these figures were 5.95%(±0.01%) versus 5.79%, cancer 0.85%(±0.003%) versus 0.91%, coronary heart disease 3.89%(±0.01%) versus 3.67%, chronic kidney disease 2.48%(±0.02%) versus 2.33%, chronic obstructive pulmonary disease 1.57%(±0.01%) versus 1.48%, dementia 0.47%(±0.003%) versus 0.42%, diabetes 3.52%(±0.01%) versus 3.65%, epilepsy 0.63%(±0.002%) versus 0.62%, heart failure 0.88%(±0.004%) versus 0.80%, hypertension 12.67%(±0.03%) versus 12.56%, learning disability 0.30%(±0.002%) versus 0.27%, mental health 0.74%(±0.004%) versus 0.72%, obesity 8.29%(±0.04%) versus 7.50%, palliative care 0.11%(±0.002%) versus 0.09%, stroke/transient ischaemic attack 1.89%(±0.01%) versus 1.65%, hypothyroidism 2.74%(±0.01%) versus 2.63%. **CONCLUSIONS:** THIN and national crude prevalences were close but higher in THIN except for cancer and diabetes. Differences are likely to be due to factors not controlled for such as demographics, socioeconomics, practice infrastructure, and community.

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ARE INCREMENTAL BENEFITS FROM MEDICAL CARE DECREASING? AN ANALYSIS OF QALY GAINS OVER TIME

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OBJECTIVES: As medical care advances, new and innovative interventions may offer more limited benefits compared with existing standard of care, which already include important background technologies (e.g., statins, effective chemotherapy). We analyze changes in incremental QALY gains over time, as reflected in cost-utility analyses (CUAs). **METHODS:** We used the Tufts Medical Center Registry of original CUAs published through 2007 (www.cearegistry.org) (N = 1704) to determine the year of publication, type of disease studied, and the incremental QALYs gained for each intervention over a comparator. We used linear regression analysis to examine changes in incremental QALYs gained by year of CUA publication. Our analysis is restricted to CUAs published between 1995 and 2007. As each CUA may report multiple incremental cost-effectiveness ratios (ICER), our primary analysis is restricted to studies reporting a single incremental value of QALYs gained. In a secondary analysis we analyzed QALY gains in all CUAs. Because the distribution of QALY gains reported in CUAs is skewed, we log transformed these gains before conducting the regression. **RESULTS:** We analyzed 614 interventions, resulting in a geometric mean (median) gain of 0.13 (0.14) QALYs. The results of the multivariable analysis indicate that incremental QALY gains are decreasing by 13% annually (P = 0.002). Nonetheless, this phenomenon is limited, explaining only 2% of the variation in incremental QALYs. When all 2415 ICERs were analyzed, the mean (median) gain was 0.12 (0.12) QALYs and QALY gains are decreasing by 19% annually ($p < 0.0001$). Our model,